



FAMILY OFFICE INSIGHTS

facilitated by The Bavelas Group

February 2020

Vol 7 | Issue 285

Peer Insights

R E P O R T

Q&A with John MacMahon, Mitre Medical CEO

Principle Series:

Mitre Medical is committed to eliminate the need for open heart surgery for patients with functional mitral regurgitation (FMR) and at risk of heart failure. The most common cardiovascular surgery is the coronary bypass procedure. Bypass patients also have FMR 30% of the time, and the presence of significant FMR doubles the 5-year mortality rate in these patients. Patients and surgeons would prefer a safe and effective FMR treatment to be performed at the same time as their bypass procedure. Unfortunately, adding the present standard of care, mitral annuloplasty, triples the risk of neurological complications including stroke, doubles the risk of AFib, and adds three days to the hospital stay to the bypass procedure. The result is less than 4% of bypass patients have their FMR treated at the same time.

We fill the needs of patients, surgeons and hospitals with a simpler, safer and more effective option for FMR. In our initial clinical study using our Mitral Touch, we have treated FMR without the need for open heart surgery. We are raising money to bring this product through the FDA approval process.

Functional MR is driven by an enlarged heart, specifically the left ventricle. When it enlarges, it deforms its associated mitral valve, which begins to leak. This is known clinically as mitral regurgitation (MR). The surgical correction of this valve was developed over 40 years ago and requires open heart surgery to restore the geometry of the deformed mitral valve from inside the heart. This standard of care does nothing to treat the underlying cause of left ventricle enlargement, which is why the FMR returns in 30% of patients at 1 year.

The inventors of our Mitral Touch were cardiac surgeons who realized that if you could change the geometry of both the mitral valve and the left ventricle from the outside of the heart, you could have a simpler and safer procedure and a more effective device. We have confirmed our Mitral Touch can treat the mitral valve without stopping the heart, and for the first time, reduce the left ventricle as well. This was demonstrated by the outstanding results from our initial clinical trial in Europe. Our company, Mitre Medical, is a team of medical device entrepreneurs that operates as an extension of Research and Development for global publicly traded MedTech companies. Our CEO has 4 previous start-ups which all have been acquired for a total of >\$600M in exit value. Our team includes world-leading researchers in cardiac surgery, including Michael Mack, MD of Baylor and Isaac George, MD of Columbia Presbyterian in New York City.

We are raising \$12M in equity capital to bring this product to US patients as soon as possible through our recently FDA approved Feasibility Study. So join us as we transform the standard of care in FMR patients by eliminating the need for open heart surgery, while providing the potential for an excellent return on your investments at the same time.



Mitre Medical



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Is the Mitral Touch entering an established market or making a new one?

We are expanding the surgical market for Functional MR patients to include the large volume of presently under-treated patients by providing a safer, simpler procedure and a more effective device.

For example, there are ~190,000 coronary artery bypass procedures in the US each year and 30% (>50,000 patients) also have clinically significant functional MR, which is an independent risk factor that can double 5-year mortality. Surgeons add treatment for their FMR in less than 10,000 of these patients because the standard of care requires a technically demanding open heart procedure with known risks of stroke, AFib and extended hospital stays. This leaves >30,000 FMR patients leaving the operating room under-treated.

Surgeons would treat these patients immediately if they had a safer, more effective device. The standard of care device only treats the mitral valve and not the left ventricle. Recent clinical trials have shown that to reduce hospitalizations and increase survival you must impact the geometry of the left ventricle.

Our Mitral Touch will immediately provide the >30,000 under-treated patients a beating heart option that includes supporting the left ventricle to improve their outcomes and reducing their hospital stays without the risks of open heart surgery.

As an investor, is the functional mitral regurgitation market seeing active exits/acquisitions?

Start-ups treating heart failure and mitral valve disease have been the most active cardiovascular acquisitions. There have been over \$5 billion dollars in this field of these medical device start-ups in the past 5 years.

Even with all these acquisitions, no device has solved the FMR patient's need for treating both their MR and left ventricle dilation. Mitre is the only surgical start-up that treats both by design.

All of these acquisitions have occurred prior to FDA approval of these devices. Mitre is expecting to achieve FDA approval with this round of funding, making this a timely opportunity for investors.

Are there additional growth markets for the Mitral Touch?

Absolutely.

Our FDA approved clinical protocol involves treating patients already in the operating room that also have functional MR. This is a well-documented unmet clinical need for surgeons and patients and is described as a concomitant market. There are 10x more patients in the US with heart failure and healthy coronaries. The majority of these patients have FMR as the primary cause of their heart failure. This large patient population is the main driver in the early and extensive acquisitions in the space as companies make bets on technologies that can help the heart failure patients who have failed medical therapy and have FMR.

These patients represent a stand-alone procedure. Those with enlarged ventricles presently have poor prognosis and no therapeutic option, and they are not presently referred to the cardiac surgeon.

With successful clinical data, the heart failure specialists that manage these patients will want to refer their patients for the Mitral Touch stand-alone option. We are already presenting the clinical data to date at Heart Failure conferences. A subsequent clinical study would be needed to confirm the efficacy in these patients.

This patient population is 10x the existing bypass + FMR surgical market. We want to be there for them as well.



John MacMahon, Mitre Medical

John MacMahon is a serial entrepreneur trained in the discipline of BioDesign. John has spent his career generating shareholder value for early-stage medical device start-ups. He has invented and/or brought through first clinical studies multiple technologies to treat unmet clinical needs for patients suffering from acute heart attacks, functional mitral regurgitation, hypertension and stroke prevention.

These start-ups have generated exits in excess of \$600M in shareholder value. As founder and CEO of Kerberos Proximal Solutions (sold to Fox Hollow Technologies), as COO for Maya Medical (sold to Covidien) and as the General Manager for Claret (sold to Boston Scientific), John has built teams that balance excellent engineering with front-line clinicians from around the world for the benefit of patient's lives.

Just as important as shareholder value creation, clinical impact has been exemplary, with two of these products maintaining the most effective peer-reviewed results in their respective fields. Most recently, the Sentinel from Claret Medical remains the only FDA approved device for stroke prevention during TAVR, reducing the risk of stroke by more than 50%, providing the acquiring company, Boston Scientific first mover position in this important field.

Presently as CEO of Mitre Medical, John is leading a team dedicated to transforming the treatment of heart failure by cardiac surgeons. The Mitral Touch provides a minimally invasive beating heart option to treat the heart as a unified structure. This requires treating both the mitral regurgitation and left ventricular dilation with a single device — an elegant and disruptive approach that addresses the fundamentals of heart failure without the need for open heart surgery.

Mr. MacMahon studied Physics as an undergraduate at University of California, Santa Cruz, where he won the UCSC Chancellor's Award for his research on synthetic aperture radar imaging. He attended graduate school at Stanford University, where he studied Biomechanical and Electrical Engineering, where he shared a Whitaker Fellowship under Drs. Dennis Carter and Tom Andriacchi in orthopedic biomechanics. His career path was determined when he attended the course Medical Device Start-Up 101 Seminar Sponsored by Wilson Sonsini and Dr. Paul Yock. The program was the precursor of Stanford BioDesign, where John continues to support the next generation of Medical Device entrepreneurs. Contact John jmacmahon@mitremedical.com